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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/127,624	08/03/1998	F. ABEL PONCE DE LEON	002076-007	1506

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EXAMINER

WILSON, MICHAEL C

ART UNIT

PAPER NUMBER

1633

DATE MAILED: 01/23/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Advisory Action

Application No.

09/127,624

Applicant(s)

Ponce De Leon et al.

Examiner

Michael C. Wilson

Art Unit

1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED Jan 14, 2002 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

Therefore, further action by the applicant is required to avoid the abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

## THE PERIOD FOR REPLY [check only a) or b)]

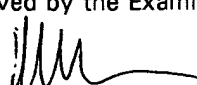
- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
- b) ☐ In view of the early submission of the proposed reply (within two months as set forth in MPEP § 706.07 (f)), the period for reply expires on the mailing date of this Advisory Action, OR continues to run from the mailing date of the final rejection, whichever is later. In no event, however, will the statutory period for the reply expire later than SIX MONTHS from the mailing date of the final rejection.

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on \_\_\_\_\_. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will be entered upon the timely submission of a Notice of Appeal and Appeal Brief with requisite fees.
3. ☒ The proposed amendment(s) will not be entered because:
- (a) ☒ they raise new issues that would require further consideration and/or search. (See NOTE below);
- (b) ☐ they raise the issue of new matter. (See NOTE below);
- (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without cancelling a corresponding number of finally rejected claims.

NOTE: the limitations in claims 41 and 42 would require enablement and art considerations not previously required.

4. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_
5. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment cancelling the non-allowable claim(s).
6. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because:  
see attached
7. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
8. ☒ For purposes of Appeal, the status of the claim(s) is as follows (see attached written explanation, if any):  
Claim(s) allowed: \_\_\_\_\_  
Claim(s) objected to: \_\_\_\_\_  
Claim(s) rejected: 1, 4, 5, 7, 8, and 29-40
9. ☐ The proposed drawing correction filed on \_\_\_\_\_ a) ☐ has b) ☐ has not been approved by the Examiner.
10. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_
11. ☐ Other: \_\_\_\_\_

  
MICHAEL C. WILSON  
PATENT EXAMINER  
ART UNIT 1632

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The Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1632.

The language proposed in claim 1, ii) would be objected to because it does not accurately convey the method. Claim 1 is a "method for culturing"; therefore, step ii) should include "culturing" and media, e.g. "culturing said PGCs in media comprising LIF, bFGF, SCF, and IGF in amounts sufficient to maintain said PGCs for at least 14 days." "...culturing said PGCs in a culture medium comprising at least the following growth factors in amounts sufficient to maintain said PGCs for at least 14 days: LIF, bFGF, SCF, and IGF." would also be sufficient.

The proposed alteration in the language of claim 33, ii) would be objected to because it does not accurately convey the product. Claim 33 is a "culture"; therefore, the product should include media, e.g. "A culture comprising PCGs and media, said media comprising LIF, bFGF, SCF, and IGF in amounts sufficient to maintain said PGCs for at least 14 days." "...PGCs contained in a culture medium comprising at least the following growth factors in amounts sufficient to maintain said PGCs for at least 14 days: LIF, bFGF, SCF, and IGF." would also be sufficient.

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***Claim Rejections - 35 USC § 112***

Incorporation of claim language from claims 29 and 36 into claims 1 and 33 respectively would overcome the enablement rejection regarding the growth factors required to maintain the cells for 14 days.

Claims 32 and 38 remain rejected for reasons of record. Applicants argue methods of transfecting feeder cells were known in the art and one of skill could easily have transfected feeder cells to express LIF, bFGF, SCF, and IGF. Applicants argument is not persuasive. Slanicka and Durcova-Hills were not available to one of skill in the art at the time the invention was made. The specification does not provide adequate guidance to obtain transfected feeder cells to express LIF, bFGF, SCF, and IGF in amounts sufficient to maintain PGCs for at least 14 days. Without such guidance, it would require one of skill in the art undue experimentation to make feeder cells transfected DNA encoding LIF, bFGF, SCF, and IGF such that the feeder cells express LIF, bFGF, SCF, and IGF in amounts sufficient to maintain said PGCs for at least 14 days. Applicants argue that feeder cells known in the art serve as a source of growth factors. Applicants argument is not persuasive. Anderson was not available at the time of filing. Anderson, De Felici and Matsui do not teach feeder cells secrete LIF, bFGF, SCF, and IGF in amounts sufficient to maintain PGCs for at least 14 days. Without such guidance, it would require one of skill in the art undue experimentation to use feeder cells to obtain LIF, bFGF, SCF, and IGF in amounts sufficient to maintain said PGCs for at least 14 days.

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***Double Patenting***

Applicants request that the double patenting rejection be held in abeyance until allowable subject matter has been indicated is noted.

Inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Wilson who can normally be reached on Monday through Friday from 9:00 am to 5:30 pm at (703) 305-0120.

Questions of formal matters can be directed to the patent analyst, Dianiece Jacobs, who can normally be reached on Monday through Friday from 9:00 am to 5:30 pm at (703) 305-3388.

Questions of a general nature relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-1235.

If attempts to reach the examiner, patent analyst or Group receptionist are unsuccessful, the examiner's supervisor, Deborah Clark, can be reached on (703) 305-4051.

The official fax number for this Group is (703) 308-4242.

Michael C. Wilson



MICHAEL C. WILSON  
PATENT EXAMINER